IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	CLARKE, GRAHAM M.		
Application No.:	10/621620	Confirmation No.:	1875
Filed:	July 17, 2003	Group Art Unit	
Title:	MICRONEEDLE DEVICES AND MICRONEEDLE DELIVERY APPARATUS		

BRIEF ON APPEAL

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February 27, 2008 /Chris Johnson/

Date Signed by: Chris Johnson

Dear Sir:

This is an appeal from the Office Action mailed on July 27, 2007, in light of the Advisory Action mailed July 27, 2007, finally rejecting claims 1-18.

Fees

☒ Any required fee under 37 CFR § 41.20(b)(2) will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.17 which may be required to Deposit Account No. 13-3723.

☒ Please charge any additional fees associated with the prosecution of this application to Deposit Account No. 13-3723. This authorization includes the fee for any necessary extension of time under 37 CFR § 1.136(a). To the extent any such extension should become necessary, it is hereby requested.

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A Notice of Appeal in this application was mailed on November 27, 2007, and was received in the USPTO on November 27, 2007.

Appellants request the opportunity for a personal appearance before the Board of Appeals to argue the issues of this appeal. The fee for the personal appearance will be timely paid upon receipt of the Examiner's Answer.

REAL PARTY IN INTEREST

The real party in interest is 3M Company (formerly known as Minnesota Mining and Manufacturing Company) of St. Paul, Minnesota and its affiliate 3M Innovative Properties Company of St. Paul, Minnesota.

RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any related appeals or interferences.

STATUS OF CLAIMS

Claims 1-18 are pending. Claims 19-40 have been withdrawn from consideration.

STATUS OF AMENDMENTS

No amendments have been filed after the final rejection.

SUMMARY OF CLAIMED SUBJECT MATTER

The claims at issue concern microneedle drug deliver devices having one or more solid, tapered (e.g., pyramid shaped) microneedles with a truncated, flat tip. The term microneedle is defined in the description (page 7, first paragraph) as having a length of up to 500 micrometers. The flat tip reduces fractures of the microneedles, while still permitting penetration through the stratum corneum (page 2, lines 9-12).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-18 stand rejected under 35 USC § 102(e), as purportedly anticipated by Sherman et al. (US 2002/0020688).

ARGUMENT

The issue on appeal is straightforward: does Sherman et al. disclose truncated microneedles having a solid, flat tip of at least 20 square micrometers, as required by the present claims?

Applicants respectfully submit that Figure 11 of Sherman et al., relied upon by the Examiner, clearly does not disclose a solid microneedle structure. Moreover, where Sherman et al. does disclose solid microneedles they appear invariably to have conventional sharply pointed tips. For example, the Examiner cites paragraph 0088, but that paragraph actually supports Applicants' position (emphasis added):

> **[0088] Fig. 15A** represents an alternative embodiment in which a microneedle array **290** comprises "solid" microneedles **292** and **294**, rather than hollow microneedles as seen at **282** and **284** on FIG. 15. These solid microneedles **292** and **294** are formed by a similar mold as viewed on **FIG. 12**, but with the micropillars **222** and **224** removed from this mold, and a change in shape of the microholes **213** and **217**. This simple change allows the solid microneedles to be formed within conical microholes (not shown on **FIG. 12**), and produces a pointed conical shape, as exhibited by the outer conical wall **250** and **252** for microneedle **292**, with a top pointed surface at **296**. Similarly, the microneedle **294** has a conical outer wall **254** and **256**, with a similar top pointed surface at **298**. The other dimensions and features of the solid microneedle array **290** can be exactly the same as those features of the hollow microneedle array **280** of **FIG. 15**, or the dimensions may be different since this is for a different application.

It is clear from this paragraph, as well as Figs. 15A, 24, 26, and 29, that Sherman et al. teaches only the conventional design of solid microneedles that are pointed at the tip, presumably based on the assumption in the art that this is preferable. However, as noted in the first paragraph on page 8 of the present specification, providing the microneedles with a blunt tip rather than pointed can improve structural integrity and avoid leaving fractured needle debris in the skin. This was not recognized or disclosed by Sherman et al.

Accordingly, Applicants believe that the present claims 1-18 are clearly novel over Sherman et al.

CONCLUSION

For the foregoing reasons, appellants respectfully submit that the Examiner has erred in rejecting this application and therefore request reversal.

Respectfully submitted,

February 27, 2008
Date

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CLAIMS APPENDIX

Listing of Claims

1. (Previously Presented) A microneedle device comprising:

a substrate comprising a first major surface; and

at least one microneedle projecting from the first major surface of the substrate, the at least one microneedle comprising a base proximate the first major surface of the substrate, wherein the at least one microneedle is tapered from the base to a solid flat tip distal from the base such that the at least one microneedle comprises a truncated tapered shape;

wherein the solid flat tip comprises a surface area measured in a plane aligned with the base of 20 square micrometers or more and 250 square micrometers or less.

2. (Original) A device according to claim 1, wherein the at least one microneedle comprises a plurality of microneedles.

3. (Original) A device according to claim 1, wherein the flat tip comprises a surface area of 100 square micrometers or less.

4. (Original) A device according to claim 1, wherein the flat tip comprises a surface area of 50 square micrometers or less.

5. (Original) A device according to claim 1, wherein the at least one microneedle comprises a height above the first major surface and a maximum base dimension, the height and the maximum base dimension ratio defining an aspect ratio, wherein the aspect ratio is 2:1 or more.

6. (Original) A device according to claim 1, wherein the at least one microneedle is formed of one or more polymers.

7. (Original) A device according to claim 1, wherein the base of the at least one microneedle comprises a base area of 900 square micrometers or more.

8. (Previously Presented) A microneedle device comprising:

a substrate comprising a first major surface; and

a plurality of microneedles projecting from the first major surface of the substrate, each microneedle of the plurality of microneedles comprising a base proximate the first major surface of the substrate, wherein each microneedle of the plurality of microneedles is formed of one or more polymers and is tapered from the base to a solid flat tip distal from the base such that each microneedle of the plurality of microneedles comprises a truncated tapered shape;

wherein the solid flat tip comprises a surface area measured in a plane aligned with the base of 20 square micrometers or more and 100 square micrometers or less;

wherein the base of each microneedle of the plurality of microneedles comprises a base area of 900 square micrometers or more;

and wherein each microneedle of the plurality of microneedles comprises a height above the first major surface and a maximum base dimension, the height and the maximum base dimension ratio defining an aspect ratio, wherein the aspect ratio is 3:1 or more.

9. (Previously Presented) A microneedle device comprising:

a substrate comprising a first major surface; and

at least one microneedle projecting from the first major surface of the substrate, the at least one microneedle comprising a base proximate the first major surface of the substrate, wherein the at least one microneedle is tapered from the base to a solid tip distal from the base such that the at least one microneedle comprises a truncated tapered shape having a height (h) above the first major surface as measured from the base to the tip;

wherein the at least one microneedle comprises a solid cross-sectional area of 20 square micrometers or more and less than a base area of the at least one microneedle, where the solid cross-sectional area is measured in a plane aligned with the base, the plane being located at a distance of 0.98h from the base.

10. (Original) A device according to claim 9, wherein the at least one microneedle comprises a plurality of microneedles.

11. (Previously Presented) A device according to claim 9, wherein the solid cross-sectional area comprises 25% or less of the base area.

12. (Previously Presented) A device according to claim 9, wherein the solid cross-sectional area comprises 100 square micrometers or less.

13. (Original) A device according to claim 9, wherein the at least one microneedle comprises a height (h) above the first major surface and a maximum base dimension, the height and the maximum base dimension ratio defining an aspect ratio, wherein the aspect ratio is 2:1 or more.

14. (Original) A device according to claim 9, wherein the at least one microneedle is formed of one or more polymers.

15. (Original) A device according to claim 9, wherein the base of the at least one microneedle comprises a base area of 900 square micrometers or more.

16. (Previously Presented) A microneedle device comprising:

a substrate comprising a first major surface; and

a plurality of microneedles projecting from the first major surface of the substrate, each microneedle of the plurality of microneedles comprising a base proximate the first major surface of the substrate, wherein each microneedle of the plurality of microneedles is formed of one or more polymers and is tapered from the base to a solid flat tip distal from the base such that each microneedle of the plurality of microneedles comprises a truncated tapered shape;

wherein each microneedle of the plurality of microneedles comprises a solid cross-sectional area of 20 square micrometers or more and 25% or less of a base area of each microneedle of the plurality of microneedles, where the solid cross-sectional area is measured in a plane aligned with the base, the plane being located at a distance of 0.98h from the base;

wherein the base of each microneedle of the plurality of microneedles comprises a base area of 900 square micrometers or more;

and wherein each microneedle of the plurality of microneedles comprises a maximum base dimension, the height and the maximum base dimension ratio defining an aspect ratio, wherein the aspect ratio is 3:1 or more.

17. (Original) A method of using a microneedle device, the method comprising:
providing a microneedle device according to claim 1;
contacting the skin on a patient with the at least one microneedle;
forcing the microneedle device against the skin.

18. (Original) A method of using a microneedle device, the method comprising:
providing a microneedle device according to claim 9;
contacting the skin on a patient with the at least one microneedle;
forcing the microneedle device against the skin.

19.-40. (Withdrawn)

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.